REMARKS/ARGUMENTS

The preceding amendments and following remarks are submitted in response to the non-final Office Action mailed December 14, 2004. Claims 4-5 and 10-12 remain pending in this application. Reconsideration, examination and allowance of all pending claims are respectfully requested.

35 U.S.C. § 102(b) Rejections

In paragraph 3 of the Office Action, the Examiner rejected claims 4-5 and 10-12 under 35 U.S.C. § 102(b) as being anticipated by *Crocker* (U.S. Patent No. 5,522,800). Applicants respectfully traverse this rejection.

The *Crocker* reference discloses a catheter (10) including an elongated tubular body (12) having a proximal end (14) and a distal end (16), an inflatable balloon (28), and a movable support (50) that can be manipulated between a proximal, introductory position (Figure 4) to a distal, perfusion position (Figure 6). A number of influent and effluent fluid ports (30,32) are in fluid communication with each other via a central lumen (54), which serves the twofold purpose of carrying perfusion fluid across the site of the balloon (28) as well as receiving the guidewire. As described in *Crocker*, the central lumen (54) is configured to expand when the balloon (28) is inflated or when the movable support (50) is advanced distally within the tubular body (12). As can be seen in Figure 6 of *Crocker*, the central lumen (54) reduces in cross-sectional area at a location distally of the balloon (28), allowing the movable support (50) to be advanced to the second (*i.e.* distal) position within the balloon (28).

In contrast, claim 4 of the present invention recites:

> 4. A balloon angioplasty catheter comprising:
> an elongated catheter body having a proximal end and a distal end;

> a balloon including an inflatable envelope portion, the balloon having a proximal end and a distal end;
>
> a perfusion lumen extending through the balloon, the perfusion lumen having a proximal end and a distal end, the proximal end of the perfusion lumen being proximate the proximal end of the balloon, the perfusion lumen decreasing distally in cross section *within the inflatable envelope portion.*

(emphasis added).

As can be seen above, claim 4 recites a balloon angioplasty catheter including, among other elements, a balloon having an inflatable envelope portion, and a perfusion lumen that decreases distally in cross-section within the inflatable envelope portion. Such configuration can be clearly seen in Figure 28 of the present Application, which shows a perfusion lumen (117) decreasing distally in cross-section at a region (112) located within the inflatable envelope portion (16).

Unlike the balloon angioplasty catheter recited in claim 4, the central lumen (54) of *Crocker* does not decrease distally in cross-section within the inflatable envelope portion of the balloon (28), but instead decreases in cross-section at a location distally of the balloon (28), as described above. As such, Applicants respectfully assert that claim 4 is not anticipated by the *Crocker* reference. Moreover, because independent claim 4 is allowable, claim 5 is also allowable for the reasons stated above, and since it adds other significant elements to distinguish it from the cited prior art.

With respect to the rejection of claims 10-12, Applicants respectfully assert that the *Crocker* reference fails to disclose or suggest a balloon angioplasty catheter having a guidewire lumen being disposed through the perfusion lumen and being collapsible, during normal use, in the absence of an inserted guidewire, as recited in claim 10. In

Crocker, only the perfusion lumen (54) and not the guidewire lumen (42) is collapsible. This is apparent from col. 6, lines 56-60 of *Crocker*, which provides:

> Preferably, a stiffening wire or other stiffening structure is positioned within guidewire lumen 42 between the guidewire port and the manifold 18. Such a stiffening wire improves the pushability of the catheter, as will be understood by one of skill in the art.

Thus, as can be seen above, the *Crocker* reference appears to suggest a stiffened guidewire lumen that would not collapse, during normal use, in the absence of an inserted guidewire, as recited in claim 10. Since *Crocker* fails to disclose or suggest this feature, Applicants respectfully assert that claim 10 is patentable over the cited prior art. Moreover, because independent claim 10 is allowable, claims 11-12 are also allowable for the reasons stated above, and since they add other significant elements to distinguish them from the cited prior art.

In paragraph 4 of the Office Action, the Examiner further rejected claims 4-5 under 35 U.S.C. § 102(b) as being anticipated by *Songer et al.* (U.S. Patent No. 4,892,519). Applicants respectfully traverse this rejection.

As discussed above, claim 4 of the Application recites a balloon angioplasty catheter including, among other elements, a balloon having an inflatable envelope portion, and a perfusion lumen that decreases distally in cross-section within the inflatable envelope portion of the balloon. The *Songer et al.* reference, in contrast, fails to disclose or suggest this feature. As can be seen in Figure 2 of *Songer et al.*, the perfusion lumen (19) formed by the inner tubular member (11) appears to have a uniform cross-sectional within the distensible portion of the balloon (17), and thus does not decrease distally in cross-section. As such, Applicants respectfully assert that claims 4-5 are also patentable over the *Songer et al.* reference.

In paragraph 6 of the Office Action, the Examiner rejected claims 4-5 and 10-12 under 35 U.S.C. § 103(a) as being unpatentable over *Conway et al.* (U.S. Patent No. 4,877,031) in view of *Uldall et al.* (U.S. Patent No. 5,106,368). The Examiner states that *Conway et al.* disclose the use of a perfusion dilation catheter comprising a guidewire lumen, a perfusion lumen, and a balloon, wherein the perfusion lumen includes a metallic ribbon coil support. The Examiner acknowledges that *Conway et al.* does not disclose the use of a collapsible tube for the guidewire lumen. The Examiner states, however, that *Uldall et al.* disclose this feature.

Applicants respectfully assert that claims 4-5 and 10-12 are not obvious in view of *Conway et al.* either alone or in combination with the *Uldall et al.* reference. With respect to claims 4-5, the *Conway et al.* reference fails to disclose or suggest a perfusion lumen that decreases distally in cross-section within the inflatable envelope portion of a balloon. Instead, as can be seen in Figure 1, the perfusion lumen (21) of the perfusion dilation catheter (10) of *Conway et al.* appears to have a uniform cross-section within the balloon (13). The *Uldall et al.* reference similarly fails to disclose or suggest this feature.

To establish a *prima facie* case of obviousness, all of the claim limitations must be taught or suggested by the prior art. *See* MPEP at § 2143.03. Moreover, there must be a suggestion or motivation in the prior art reference to modify the reference or combine the teachings with the knowledge available to one of ordinary skill in the art. *See Id.* at § 2142. The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art suggests the desirability of the combination. *See In re Mills*, 916 F.2d 680, 16 U.S.P.Q.2d 1430 (Fed. Cir. 1990).

Since none of the cited references, either alone or in combination, disclose or suggest a balloon angioplasty catheter having a perfusion lumen decreasing distally in cross section within an inflatable envelope portion of a balloon, Applicants respectfully assert that claim 4 is patentable over the cited prior art. For these and other reasons, Applicants respectfully submit that dependent claim 5 is also patentable over the cited prior art.

With respect to the obviousness rejection of claims 10-12, Applicants assert that the *Conway et al.* reference and *Uldall et al.* reference similarly fail to teach each and every limitation of those claims. Independent claim 10 of the present Application recites:

> 10. A balloon angioplasty catheter comprising :
> an elongated catheter body;
> a balloon;
> a perfusion lumen extending through the balloon, the perfusion lumen having a distal end and a proximal end;
> a guidewire lumen, the guidewire lumen being disposed through the perfusion lumen and being collapsible, during normal use, in the absence of an inserted guidewire.

As can be seen above, claim 10 recites a balloon angioplasty catheter including a guidewire lumen being disposed through a perfusion lumen and being collapsible, during normal use, in the absence of an inserted guidewire. Such configuration can be clearly seen, for example, in Figures 36-38 of the Application, which show a guidewire lumen (313) disposed through the perfusion lumen (217) in an un-collapsed position A and a collapsed position B.

Neither the *Conway et al.* reference nor the *Uldall et al.* reference disclose or suggest a guidewire lumen disposed through a perfusion lumen and being collapsible, during normal use, in the absence of an inserted guidewire, as recited in claim 10. As shown in Figure 4 of *Conway et al.*, the two lumens (20,21) formed by the perfusion

body (12) of the perfusion dilation catheter (10) have a side-by-side or lateral arrangement, with the guidewire lumen (20) being separated from the perfusion lumen (21) by an interior wall of the perfusion body (12). As such, the *Conway et al.* reference does not disclose or suggest a guidewire lumen disposed through a perfusion lumen and being collapsible, during normal use, in the absence of an inserted guidewire.

The *Uldall et al.* reference similarly fails to disclose or suggest this limitation. As shown in Figure 3 in *Uldall et al.*, a thick-walled elongated tubular member (201) is attached laterally to a thin-wall tubular member (204), forming two lumens (204,205) having a side-by-side or lateral arrangement. In addition, and as is further described in *Uldall et al.*, the un-collapsible lumen (204) formed by the thick-walled tubular member (204) and not the collapsible lumen (205) formed by the thin-wall tubular member (205) is configured to receive a guidewire 110. Thus, the *Uldall et al.* reference fails to disclose or suggest a guidewire lumen being disposed through a perfusion lumen and being collapsible, during normal use, in the absence of an inserted guidewire.

Applicants further assert that there is no motivation to combine references since *Conway et al.* teaches away from the use of a collapsible guidewire lumen. Col. 5, lines 18-30 of the *Conway et al.* reference provides:

> The tubular member 11 can be formed of suitable thermoplastic material such as polyethylene, polyvinylchloride and the like or from stainless steel (i.e. hypotubing) or it can be of composite structure such as described, in copending application Ser. No. 241,047 filed 9-6-88. In this latter application, the composite structure comprises a tubular substructure formed from material such as polyimide with an outer coating of resin impregnated fibrous material which has been wound or braided into the tubular substructure *to provide a relatively stiff proximal portion and a relatively flexible but diametrically rigid distal portion.*

(emphasis added).

Thus, as can be seen above, the *Conway et al.* reference appears to suggest the desirability of a tubular member (11) having a relatively stiff proximal portion and a relatively flexible but diametrically rigid distal portion. Since *Conway et al.* teaches away from the use of a collapsible guidewire lumen, as recited in claim 10, Applicants respectfully assert that there is no motivation to combine *Conway et al.* with that taught in *Uldall et al.*

Since the *Conway et al.* and *Uldall et al.* references fail to teach each and every claim limitation, and since there is no motivation to combine references, Applicants respectfully assert that claim 10 is patentable over the cited prior art. Moreover, because claim 10 is allowable, dependent claims 11-12 are also allowable for the reasons stated above, and since they add other significant elements to distinguish them from the cited prior art

Reexamination and reconsideration are respectfully requested. It is respectfully submitted that the claims are now in condition for allowance, issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

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By their Attorney,

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